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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,915	01/18/2002	Jennifer Hillman	PF-0722 USN	1605

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EXAMINER	
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ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,915	HILLMAN ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 8, 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13,15-19,22,25,26 and 28-195* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,11,16,17,59,105,151 and 184-195* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 8,10,13,15,18,19,22,25,26,28-58,60-104,106 150 and 152-183.

This Office Action is in response to the paper filed June 8, 2004. Claims 12, 14, 20, 21, 23, 24, and 27 have been canceled. Claims 8, 10, 13, 15, 18, 19, 22, 25, 26, 28-58, 60-104, 106-150, and 152-183 have been withdrawn from further consideration by the Examiner because these claims are drawn to non-elected inventions. Claims 1-7, 9, 11, 16, 17, 59, 105, 151, and 184-195 under currently under examination.

Priority is set to November 10, 1999, in which SEQ ID NO: 14 of provisional application 60/164,647 is instant Claim 36. Other provisional applications should be deleted from the priority listing.

Withdrawal of Objections and Rejections

The objection to the disclosure because it contains an embedded hyperlink and/or other form of browser-executable code is withdrawn.

Maintenance of Rejections

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7, 9, 11, 16, 17, 59, 105, 151, and 184-195 are again rejected under 35 U.S.C. 101 the claimed invention lacks patentable utility. It does not appear that the information provided in the specification regarding the polynucleotides having SEQ ID NO: 90 and encoding the polypeptide having SEQ ID NO: 36 is accurate or complete. Thus, the claimed products are not useful.

At page 8 of the specification, the encoding polypeptide having SEQ ID NO: 36 is said to be one of 54 cell cycle and proliferation proteins (CCYPR), specifically referred to as CCYPR-36.

As a whole, these CCYPRs and polynucleotides encoding them are stated to be useful for the diagnosis, prevention, and treatment of immune, developmental, and cell signaling disorders, and cell proliferation disorders including cancers (page 8, para. 1). No specific activity is exemplified or attributed to any of the 54 CCYPRs, and no direction on how the any of the polynucleotides can be used in such a manner is provided.

The encoded polypeptide having SEQ ID NO: 36 is stated in Table 2 at page 87 to have homology to malignant brain tumor protein, which is cited to Koga et al. (1999; Oncogene 18:3799-3809). Koga et al. describes the human homology of *Drosophila* lethal (3) malignant brain tumor (l3mbt) protein, a tumor suppressor protein. In contrast to the 445 amino acid sequence of SEQ ID NO: 36, Koga et al. describes h-l(3)mbt as having 772 amino acids. Thus, the instant CCYPR-36 is a much shorter amino acid sequence that the h-l(3)mbt protein which the specification looks to for utility and enablement. The polynucleotide sequence encoding h-l(3)mbt is 3394 nucleotides and maps to chromosome 20, and is a single open reading frame encoding the 772 amino acid sequence. See Koga et al. at page 3800, Fig1A; page 3801, Fig 1C and right col. An alternative splice isoform (page 3802) was also identified as having 738 amino acids.

At page 28 of the specification, the polynucleotides having SEQ ID NO: 90 (encoding SEQ ID NO: 36) is said to map to chromosomes 2, 3, and 6. It is not possible for a specific nucleotide sequence comprising 2555 nucleotides to be found on three different chromosomes. Further, this is incongruent with Koga et al. who state that the polynucleotides encoding h-l(3)mbt protein maps to chromosome 20.

Therefore, given that the polynucleotides SEQ ID NO: 90 is taught in the specification to map to chromosomes 2, 3, and 6, rather than chromosome 20 as taught in the cited reference Koga et al., and the encoding polypeptide having SEQ ID NO: 36 is over 220 amino acids shorter than the h-l(3)mbt taught in Koga et al., the specification does not provide a basis for stating

that the polypeptide and encoding polynucleotides have homology, and therefore implied potential like activity, to h-l(3)mbt as taught in Koga et al.

Perusal of additional art also provides evidence that Applicants are not in any meaningful possession of a malignant brain tumor protein, or its encoding polynucleotides. Wismar et al. (2001; FEBS Letters 507:199-121) teach human lethal (3) malignant brain tumor-like 2 protein (LML2), which is a 705 amino acid polypeptide that encompasses all of SEQ ID NO: 36 from amino acids 211-705 of LML2. Thus, Wismar et al.'s LML2 comprises a 210 amino acid N-terminus when compared to SEQ ID NO: 36, and this additional length is similar to that described in Koga et al. The polynucldotide encoding LML2 encompasses SEQ ID NO: 90, and maps to chromosome 22.

In total, the polynucleotides encoding SEQ ID NO: 36, or the polypeptide having SEQ ID NO: 36 lack utility because Applicants are not in possession of either full-length product, and the specification provides information that is incongruent and/or lacking when the products are compared to the art of record. One skilled in the art could not identify these products as they are set forth in the specification if they were to come upon them in the lab or reading art references, for example. These products do not exist as described.

Claims 1-7, 9, 11, 16, 17, 59, 105, 151, and 184-192 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a the asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicants argue broadly (page 29) then specifically to SEQ ID NO: 36 (page 30) that even if SEQ ID NO: 36 is over 220 amino acids shorter than Koga et al.'s h-l(3)mbt, this does not mean that the claimed polypeptides do not have activity similar to the Koga et al. protein.

Applicants urge that fragments of larger proteins can have the function of the larger protein. Further, that Applicants are only claiming fragments (and encoding nucleic acids) that regulate cell cycle and cell proliferation. These arguments are not responsive. Applicants are not in possession of the full-length protein and do not know if SEQ ID NO: 36 is a functional fragment of it. Additionally, the phrase "regulates cell proliferation" is broad; does it increase or decrease cell proliferation?

It is noted that Applicants do not discuss the nucleic acid sequence, or the Wismar reference.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 6, 7, 9, 11, 16, 17, and 184-195 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Claims refer to percent identity, biologically active fragments, and immunologically active fragments, polynucleotides that hybridize to claimed polynucleotides, and so forth. The specification does not describe any of these variants, or any variant having any activity. Therefore, the specification lacks written description.

Applicants urge that the amendment to the claim "regulates cell proliferation" or "capable of inducing an immune response" over comes this rejection. This activity is too broad. Does SEQ ID NO: 36 increase or decrease cell proliferation? One skilled in the art should not have

to test every possible assay listed in the specification to determine which activity is attributed to SEQ ID NO: 36. Therefore, this argument is not persuasive.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 9, 11, and 184-192 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The activity of a biologically active fragment is not set form in Claim 1, even though claim amendments have been made to recite "regulates cell proliferation" because cell proliferation can be increased or decreased. It is not clear what an immunogenically active fragment of SEQ ID NO: 36 is, that is, for example, what kind of antibody does an immunogenically active fragment generate? What is a specific immune response?

Claim 184 depends from canceled Claim 12, and has been taken to depend from Claim 1 to advance the prosecution. Claims 186 and 190 refer to hybridization but no conditions are set forth, rendering the claims indefinite.

The Claims still comprise non-elected subject matter and therefore it is indefinite what the elected subject matter is.

Applicants urge that one skilled in the art knows what a biologically active fragment is. Unless the activity is placed into the claim, it is not certain what activity is being attributed to SEQ ID NO: 36, for example. Applicants urge that the term "regulates cell proliferation" is definite. It is not clear if the cell proliferation is increased or decreased, and thus this term is also indefinite.

Applicants urge that the placement of the term "high stringency conditions" is definite. These conditions are exemplified at page 21, for specified. Thus, the term is indefinite.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen Cochrane Carlson

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER